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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/554,386	07/19/00	FABRY	B	H-3190-PCT/U

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HM12/1219

EXAMINER	
QAZI,S	
ART UNIT	**PAPER NUMBER**
1616	7

DATE MAILED: 12/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/554,386	Bernd Fabry
Examiner	**Group Art Unit**
Sabiha Qazi	1616

☒ Responsive to communication(s) filed on *Jul 19, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *11-30* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *11-30* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

First Office Action on Merits

Status of the application

Claims 11-30 are pending.

Claims 11-30 are rejected.

No claim is allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 11-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miettinen et al. (EPA 594,612) in view of Alexander et al. (The New England Journal of Medicine, Vol. 318, No. 9, pages 549-547).

Instant claims are drawn to composition, preparation and method of use comprising a at least one phytostenol ester of a conjugated fatty acid having from about 6 to about 24 carbon atoms, for lowering serum cholesterol.

Miettinen et al. teaches fatty acid composition of β-sitostanol ester mixtures containing large amount of monoenes and polyenes, whereby the efficacy in lowering the cholesterol levels in serum are

enhanced. See the entire document especially lines 40-45, and lines 56-58 on page 4. See also examples 1-3.

Instant claims differ from the reference in claiming at least one phytostenol ester of a conjugate acid for reducing the serum cholesterol whereas Miettinen et al. teaches that a mixture of β-sitostanol ester with polyenes or monoenes for lowering the cholesterol level.

Alexander et al. alleviates the deficiency of Miettinen et al. because it teaches the n-3 fatty acids for lowering the low-density lipoprotein (LDL) cholesterol. See last para of col. 2 on page 549. The reference also teach dietary fish and fish oil supplements on plasma lipid levels and reduction of triglyceride levels. See Fig. 2 for the elected species eicosapentaenoic acid.

The two references are combined because they are from the same field.

One skilled in the art would find ample motivation from the prior art supra to combine the teachings of Alexander et al. and Miettinen et al. by using sterol ester and omega-3 fatty acid of known properties where the results obtained thereby are no more than the additive effects of the ingredients. In this case sterol ester and omega-3 fatty acid or ester are well known dietary supplements for lowering the cholesterol and triglyceride levels.

It would have been obvious to one skilled in the art to be motivated to prepare an stanol ester with unsaturated fatty acid to reduce the serum cholesterol because prior teaches that unsaturated fatty acid especially omega-3 fatty acid posses excellent property of reducing the serum cholesterol. Instant composition and methods would have been obvious to one skilled in the art at the time of invention.

It is a prima facie case of obviousness for one skilled in this art to use in combination two or more compositions that have been used separately for the same purpose in order to form a third composition useful for the same purpose.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

2. Claims 11-30 are rejected under 35 U.S.C. 103 as being unpatentable over Burdick et al. (EP 1,004,594) . Burdick et al. teaches the composition of phytosterol and/or phytostanol esters with polysaturated fatty acids having 18-22 carbon atoms, which embraces applicant's claimed invention. See the entire document especially abstract and lines 3-10 on page 3 [0013]. . These compositions are taught to be useful for reducing serum cholesterol and triglyceride. See sections [0015] to [0022] on page 3; table 1-5 on pages 4-5.

Instant claims differ from the reference by claiming carbon nos of conjugated acid from 6-24 where as prior art teaches from 18-22 carbon atoms. As can be seen that prior art teachings are obvious as carbon no. overlaps with the prior art teachings.

It would have been obvious to one having ordinary skill in the art at the time of the invention to select any taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole, i.e., as useful for lowering serum cholesterol .

One having ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merck & Co. V. Biocraft Laboratories, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Minor Informalities

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

S. Qazi

Sabiha N. Qazi, Ph.D.

Primary Examiner

Art Unit 1616

12/17/00